FORUM OF END STAGE RENAL DISEASE NETWORKS

President
David Henner, DO
Pittsfield, MA

President-Elect
Kam Kalantar-Zadeh, MD, MPH, PhD
Irvine, CA

Secretary
Chris Brown
Cranbury, NJ

Treasurer
Stephanie Hutchison, MBA
Seattle, WA

Past-President
Ralph Atkinson III, MD
Nashville, TN

EDAC Chair
Brandy Vinson
Richmond, VA

MAC Chair
Kam Kalantar-Zadeh, MD, MPH, PhD
Irvine, CA

KPAC Co-Chair
Derek Forfang
San Pablo, CA

EDAC Vice-Chair
Vicky Cash
Beachwood, OH

KPAC Co-Chair
Dawn Edwards
Jamaica, NY

Members-At-Large
Christine Logan, MD, FASN
Seattle, WA

Kelly M. Mayo, MS
Tampa, FL

Keith Norris, MD, PhD
Los Angeles, CA

Stephen Pastan, MD
Atlanta, GA

Katrina Russell, RN, CNN
Seattle, WA

Preethi Yerram, MD, MS, FASN
Columbia, MO

Ad Hoc Members
Andrew Howard, MD, FACP
Walnut Creek, CA

Donald A. Molony, MD
Houston, TX

John Wagner, MD, MBA
Brooklyn, NY

Louis Diamond, MB, ChB, FACP
Washington DC

Forum Coordinator
Dee LeDuc
Birchwood, WI

September 29, 2021

Mr. Ian Jamieson, M.B.A., M.H.A.
Chair, Membership Professional Standards Committee (MPSC)
Ms. Sally H Aungier
Liaison, Membership Professional Standards Committee (MPSC)
Organ Procurement & Transplantation Network, UNOS, HRSA, DHHS
PO Box 2484
Richmond, VA 23218

Re: Policy Proposal Public Comment: Enhance Transplant Program Performance Monitoring System

Dear Mr. Jamieson and Ms. Aungier,

The mission of the National Forum of ESRD Networks is to support, and to advocate on behalf of, the ESRD Networks, and to improve the quality of care for patients with kidney disease. The Forum appreciates the opportunity to comment on the policy proposal of the Membership and Professional Standards Committee (MPSC): Enhance Transplant Program Performance Monitoring System.

We support the use of program metrics to regulate medical organizations, and recognize their central importance in improving the quality of patient care and patient safety. The ESRD Networks hold the CMS contracts for overseeing quality of care for patients with kidney failure and are charged with improving the performance metrics of more than 7,500 dialysis clinics in the United States that serve more than 550,000 dialysis-dependent patients. We are patient advocates and are committed to working to increasing transplant access for all patients on dialysis through quality improvement initiatives in accordance with the scope of work outlined in CMS contracts.

We are writing to strongly recommend removing the proposed waitlist mortality ratio metric. Although we agree with the goal of reducing the mortality of all ESRD patients, including those on the kidney transplant waiting list, we are concerned this proposal will have significant unintended consequences. We believe this proposal will lead to substantial restriction in patient's access to kidney transplantation, and will worsen disparities in access for minority populations, and for patients with lower socioeconomic status, who may be considered as high-risk candidates for waitlisting. We believe this proposal will lead to transplant centers waitlisting only the healthiest patients and turning down sicker patients who are at higher risk for mortality. We are aware of patients who have already had their transplant candidacy declined by transplant

centers, in anticipation of this new quality metric. The MPSC has argued that statistical adjustments for comorbidities will account for patient differences making it unnecessary for transplant centers to avoid sicker patients, but we do not believe the available data on patient comorbidities is granular enough, or accurate enough, to make an adequate adjustment. The main source of comorbidity data, the 2728 form, is known to be prone to significant inaccuracies, particularly regarding comorbidities, and will also not reflect changes in comorbidities that occur after dialysis initiation. We also know that in the real world transplant centers' behavior may be affected by the perception that listing sicker patients will lead to a higher adjusted waitlist mortality ratio and will cause centers to reduce listing of sicker patients. This is of special concern for patients living in states with extremely long waiting times, such California, where patients can be expected to develop significant comorbidities after many years of dialysis. Because minority patients, and those of low socioeconomic status, often have a higher disease burden, as well as reduced access to care for comorbidities such as diabetes, peripheral vascular disease, and heart disease, which contribute to excess mortality, the negative consequences of the proposed policy may exacerbate already significant health disparities in access to renal transplantation.

Not only will patients be adversely affected, but reduced waitlisting will also adversely affect dialysis clinics. Currently the Percentage of Prevalent Patients Waitlisted (PPPW) is a CMS quality metric for all US dialysis clinics. This has had a positive impact as it has focused dialysis clinic's quality improvement efforts on helping patients move towards renal transplant, and has spurred a previously unseen degree of cooperation between dialysis clinics and transplant centers. While PPPW is currently only a reporting metric, in the future it will become part of the ESRD Prospective Payment System -- dialysis clinics with low waitlisting rates will be financially penalized.

This proposal creates a competing measure that undermines government policy. CMS has set a national goal of increasing the number of dialysis patients on the transplant waitlist of 20% by 2026, while UNOS is proposing a metric that may lead to reduced waitlisting.

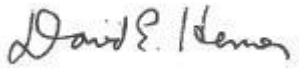
The ESRD Networks themselves may also be adversely affected by this proposed waitlist mortality ratio metric. The Networks have been charged by CMS with working with dialysis units to increase transplant waitlisting in each of their geographic areas. Often this means identifying low performing clinics and helping them generate and execute a quality improvement plan. Reduced waitlisting will make it more difficult for Networks to reach their individual CMS-mandated goals.

After reviewing this OPTN proposal Derek Forfang, Co-Chair of the Forum's Kidney Patient Advisory Council (KPAC), shared the following: **"With this mortality metric I may not have had the chance to get my kidney transplant.** I have lived with kidney disease for 23 years while, like many kidney patients, also managing diabetes and cardiovascular disease. I have used PD and incenter hemodialysis and had several complications and hospitalizations. Living in California and having to wait 12 years for an opportunity to receive the gift of a kidney transplant was a challenge. I was considered a high-risk patient at the time of transplant. Since my transplant in 2013 my heart function has improved, and I have not been hospitalized for any heart related or kidney related issues and live a very full and joyful life."

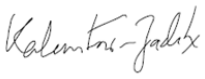
In summary, the National Forum of ESRD Networks is deeply concerned that the new proposed waitlist mortality metric will result in reduced transplant waitlisting, adversely affecting dialysis patients, and exacerbating health disparities. The adoption of this metric may also adversely affect dialysis clinics, and ESRD networks, by making it more difficult for them to meet their quality improvement goals of increasing waitlisting of dialysis patients. We believe this policy proposal conflicts with CMS quality directives to improve transplant waitlisting. We recommend that UNOS does not adopt this proposed quality metric.

Sincerely,

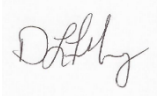
Stephen Pastan, MD
Member, National Forum of ESRD Networks Board of Directors



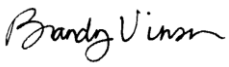
David E. Henner, DO
President, Forum of ESRD Networks



Kam Kalantar-Zadeh, MD, MPH, PhD
Chair, Forum Medical Advisory Council



Derek Forfang
Co-Chair, Forum Kidney Patient Advisory Council



Brandy Vinson
Chair, Forum Executive Director Advisory Council